

REMARKS

The Final Office Action of September 27, 2005, has been considered by the Applicants. None of the pending claims have been amended. Claims 1, 2, 4-8, and 10-33 remain pending in the Application. Reconsideration of the Application is requested.

Claims 1, 2, 4-7, 10-17, and 19-28 were rejected under 35 U.S.C. 103(a) as obvious over Scheibl or Dugger in view of Borkan. Additionally, claims 1, 2, 4-7, 10-17, and 19-30 were rejected under 35 U.S.C. 103(a) as obvious over Scheibl or Dugger in view of Ebert. Furthermore, claims 8 and 31-33 were rejected under 35 U.S.C. 103(a) as obvious over Dugger in view of Ebert and Oohashi. Claim 18 was also rejected as obvious over Scheibl or Dugger in view of Mehta.

Because Applicants traverse the rejections on the same basis, they will be addressed together.

Applicants agree that the claims should be evaluated as product-by-process claims. However, Applicants disagree that the cited references teach the same product. As discussed in the prior amendment of 11 July 2005, none of the cited references (Scheibl, Dugger, Borkan, Ebert) teach or suggest aging the fill material of the capsule. Oohashi, the newly cited reference, does not teach or suggest aging the fill material either. This process step results in a product which is different and non-obvious over the prior art.

On page 6 of the Final Office Action, the Examiner states that Ebert teaches drying the freshly made capsule; this drying is analogized to aging. However, Ebert does not teach aging the fill material, as recited in the instant claims. It is necessary to dry the capsule, and Applicants describe this step in the specification as well. This clearly indicates that the process step of aging the fill material is distinct from the step of drying the freshly made capsule. Thus, Ebert does not provide motivation to produce the claimed product. Therefore, Ebert does not render the instant claims obvious.

The product of the instant claims is different and non-obvious from prior art products. The claimed fill material is different and non-obvious because aging the fill material imparts structural differences to the fill material which results in the capsule having superior taste compared to the prior art. Soft capsules wherein the fill material is aged are directly compared to soft capsules where the fill material is not aged in the specification

from page 36, line 17, to page 38, line 24 (encompassing Production Examples 29 and 30, Example 12, and Figures 2-4). Figure 2 shows that a structural property, hardness, varies by the aging temperature. Figure 3 shows that hardness varies by the amount of time the fill material is aged. Figure 4 shows that the aging process results in a capsule having superior taste compared to a soft capsule wherein the fill material is not aged. These disclosures clearly show that the fill material is different from the fill material of the prior art. Thus, the claimed soft capsule is a different product from the prior art and the product-by-process claims are non-obvious.

Oohashi provides no motivation to combine. The Examiner states that one of ordinary skill in the art would use the additives of Oohashi because they improve mucosal absorption. However, this is incorrect. Oohashi teaches pharmaceuticals that can be administered by suppository or through mucosal absorption (collunarium) (col. 3, lines 17-24). Oohashi then lists, *in separate paragraphs*, additives suitable for each administration route. Cacao butter, coconut oil, lard, and macrogol are described as additives for suppository administration, not mucosal absorption (col. 3, lines 30-45). Examples 1-3 and 5-8 are all described as suppositories and use additives listed in the same paragraph as cacao butter, coconut oil, lard, and macrogol. Example 4 is described as a collunarium and uses an additive from the paragraph listing additives for use in collunarium, not suppositories. Thus, one of ordinary skill in the art would not read Oohashi as teaching the use of cacao butter, coconut oil, lard, and macrogol to improve mucosal absorption (i.e., for oral ingestion as in the instant claims). Claims 8 and 31-33 are therefore non-obvious.

With regard to claim 18, Applicants note that any claims depending from a non-obvious claim are also non-obvious. See MPEP § 2143.03 and *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

For the above reasons, the instant claims are not obvious under § 103(a). Applicants request withdrawal of the rejections under 35 U.S.C. 103(a).

CONCLUSION

For the reasons given above, it is respectfully submitted all pending claims (1, 2, 4-8, and 10-33) are now in condition for allowance. It is believed that no reexamination or new search is required. Withdrawal of the rejections and issuance of a Notice of Allowance is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is hereby authorized to call Richard M. Klein, at telephone number 216-861-5582, Cleveland, OH.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

December 19, 2005
Date




Richard M. Klein
Reg. No. 33,000
1100 Superior Avenue
7th Floor
Cleveland, Ohio 44114-2579
(216) 861-5582

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